

# EXHIBIT C

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE**

AMGEN INC. and AMGEN	)	
MANUFACTURING, LIMITED,	)	
	)	C.A. No. 18-1064-CFC-CJB
Plaintiffs,	)	
	)	
v.	)	
	)	
HOSPIRA, INC. and PFIZER INC.,	)	
Defendants.	)	

**PROPOSED JURY INSTRUCTIONS**

imports, offers to sell, sells, or uses within the United States a product which was made outside of the United States during the time the '997 patent is in force by a process that, if performed in the United States, would infringe the claim.<sup>31</sup> However, if the product has been materially changed by subsequent processes or the product has become a trivial and nonessential component of another product, you must find Pfizer did not infringe the '997 patent.

### **E. PRIOR USE DEFENSE<sup>32</sup>**

If you find that Pfizer's accused process meets all of the limitations of the asserted claims of the '997 patent, you must decide whether Pfizer has met its burden of showing by clear and convincing evidence that it is not liable for infringement because it commercially used the subject matter of the asserted claims at least more than one year before the effective filing date of Amgen's '997 patent. This is a defense known as the "prior use defense."

In order to have prior user rights with respect to an asserted claim, Pfizer must establish by clear and convincing evidence that: (i) Pfizer, or an entity from whom Pfizer acquired the filgrastim line of business to which this defense relates, used the process that met every limitation of the asserted claims to make filgrastim that was used in activities in the United States related to premarketing regulatory review of its filgrastim product, (ii) Pfizer acted in good faith in connection with its alleged prior use, (iii) the alleged prior use was an internal commercial use or an actual arm's length sale or other arm's length commercial transfer of a useful end result of such commercial use, (iv) the alleged prior commercial use occurred at least one year prior to the effective filing date of the application for the '997 patent, and (v) the alleged prior commercial use was not abandoned.

Subject matter for which commercial marketing or use is subject to a premarketing regulatory review period during which the safety or efficacy of the subject matter is established is a commercial use for the purpose of this defense to

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<sup>31</sup> 35 U.S.C. § 271(g); *Momenta Pharm., Inc. v. Teva Pharm. USA Inc.*, 809 F.3d 610 (Fed. Cir. 2015) (explaining what "made by" a patented process means); *Bayer AG v. Housey Pharms., Inc.*, 340 F.3d 1367 (Fed. Cir. 2003) (finding infringement under this section); *Ajinomoto Co. v. Archer-Daniels-Midland Co.*, 228 F.3d 1338, 1347 (Fed. Cir. 2000) (same).

<sup>32</sup> 35 U.S.C. § 273; based on *Boston Scientific Scimed, Inc. v. Edwards Lifesciences Corp.*, No. 16-275, D.I. 562 at 42 (D. Del. Dec. 11, 2018).

infringement.

## F. WILLFUL INFRINGEMENT<sup>33</sup>

In this case, Amgen argues that Pfizer willfully infringed Amgen's patent. If you have decided that Pfizer has infringed, you must go on and address the additional issue of whether this infringement was willful. Willfulness requires you to determine whether Amgen proved that it is more likely than not that Pfizer knew of Amgen's patent and that it believed it would infringe the patent and did so intentionally. You may not determine that the infringement was willful just because Pfizer was aware of the '997 patent and infringed it. Instead, willful infringement is reserved for the most egregious behavior, such as where the infringement is malicious, deliberate, consciously wrongful, or done in bad faith.<sup>34</sup> If you find that Pfizer had a good faith reasonable belief that it would not infringe the patent, you may find the infringement was not willful.<sup>35</sup>

To determine whether Pfizer acted willfully, consider all facts and assess Pfizer's knowledge at the time of the relevant infringing act.<sup>36</sup>

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<sup>33</sup> Based on FCBA Model Jury Instructions at § B.3.10; *Orexo AB et al. v. Actavis Elizabeth LLC et al.*, Case No. 17-cv-205-CFC, D.I. 270: Proposed Final Jury Instructions (Mar. 28, 2019).

<sup>34</sup> *F'Real Foods v. Hamilton Beach*, Case No. 16-cv-41-CFC, D.I. 307-1 at 20-21 (Sept. 30, 2019).

<sup>35</sup> *See SRI Int'l, Inc. v. Advanced Tech. Labs.*, 127, F.3d 1462 (Fed. Cir. 1997).

<sup>36</sup> 35 U.S.C. § 284; *Halo Electronics, Inc. v. Pulse Electronics, Inc.*, 136 S. Ct. 1923 (2016) (preponderance of the evidence standard for finding willfulness); *Eko Brands, LLC v. Adrian Rivera Mayanez Enters., Inc.*, No. 2018-2215, slip op. at 16 (Fed. Cir. January 13, 2020) ("Under *Halo*, the concept of willfulness requires a jury to find no more than deliberate or intentional infringement."); *Arctic Cat Inc. v. Bombardier Recreational Prod. Inc.*, 876 F.3d 1350, 1371 (Fed. Cir. 2017) ("*Halo* emphasized that subjective willfulness alone—i.e., proof that the defendant acted despite a risk of infringement that was 'either known or so obvious that it should have been known to the accused infringer,'—can support an award of enhanced damages." (quoting *Halo*, 136 S. Ct. at 1930)); *WBIP, LLC v. Kohler Co.*, 829 F.3d 1317, 1341 (Fed. Cir. 2016) ("Knowledge of the patent alleged to be willfully infringed continues to be a prerequisite to enhanced damages."); *WMS*